



NTP
National Toxicology Program

NTP Testing Program Research Concepts

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**Director, Office of Nomination and Selection
National Institute of Environmental Health Sciences**

NTP Board of Scientific Counselors Meeting

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**National Institute of Environmental Health Sciences / National Institutes of Health
National Institute for Occupational Safety and Health / Centers for Disease Control
National Center for Toxicological Research / Food and Drug Administration**





What Does the NTP Study?

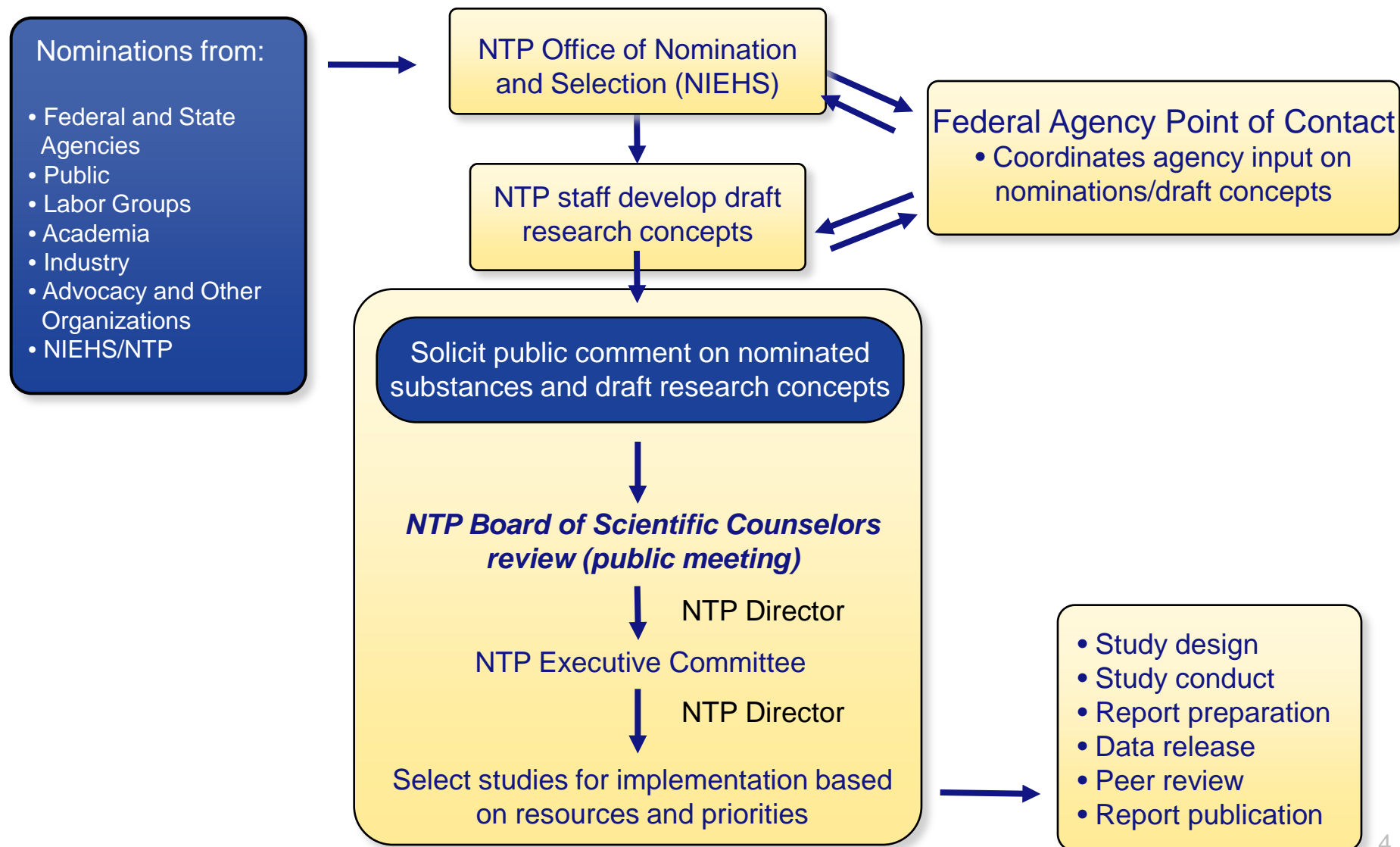
- Individual or classes of chemical, biological, or physical substances:
 - Judged to have high concern as a possible public health hazard based on the extent of human exposure and/or suspicion of toxicity
 - For which toxicological knowledge gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or evaluating dose-response relationships
- Issue-based nominations to:
 - Enhance the predictive ability of NTP toxicology studies
 - Address mechanisms of toxicity
 - Inform risk assessment approaches



Development of NTP Research Projects

- Research programs are developed in response to external and NIEHS/NTP nominations
 - Multiple levels of review to determine merit and priority for study
 - Not all nominations lead to a research program
- Iterative approach to study design, conduct and analysis
 - Phased programs with multiple review and decision points
- Incorporate novel and alternative testing approaches
 - Inform and prioritize chemical and study endpoint selection
 - Integration and interpretation of multiple data types

NTP Study Nomination Review Process





Format for Today's Session

- Introduction to testing program research concepts
- Presentation of research concepts by NTP project leader
 - Outline rationale, data gaps, key issues, hypotheses and/or specific aims to address
 - Proposed approach to address toxicological data needs for specific substance or issue, not experimental study design
 - Sufficient detail to understand scope and direction
- Public comments
- Comments from assigned Board reviewers
 - Response to charge
- Board discussion



Research Concepts for Review

- Sulfolane (Dr. Chad Blystone)
 - Groundwater contaminant nominated by multiple entities in Alaska
- Phenolic benzotriazoles (Dr. Chad Blystone)
 - NIEHS nomination to address significant data gaps for a class of high volume and environmentally persistent compounds
- Trimethylsilyldiazomethane (Dr. William Gwinn)
 - OSHA need for toxicity data based on case reports of worker deaths



BSC Review of Proposed Research Projects: Charge

- To review and comment on draft research concepts and determine whether the proposed research projects are an appropriate use of NTP testing program resources
 - A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program

BSC Review of Proposed Research Projects: Specific Comments

- Comment on the clarity and validity of the rationale for the proposed research program as articulated in the NTP research concept document.
- Comment on the merit of the proposed research program relative to the mission and goals of the NTP. *The NTP's stated goals are to: Provide information on potentially hazardous substances to all stakeholders; Develop and validate improved test methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS.*
- Based on your evaluation of rationale and merit, rate the overall significance and public health impact of this research program as low, moderate, or high. *NTP management will use this rating in assessing the relative priority of projects in the NTP's testing program.*
- Comment on the scope of the proposed program relative to your evaluation of significance and public health impact. Is the scope too broad or too limited relative to the public health importance of the substance or issue under consideration? If so, what modifications do you recommend?
- Provide any other comments you feel NTP staff should consider in developing this research program.



Questions and Comments